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10/550,991	07/13/2006	Spiros Fotinos	1581/141	4438

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,991	FOTINOS ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/18/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-50 and 63-117 have been cancelled. Claims 51-62 are under examination. The present Examiner of record has a new ground of rejection. Accordingly, this action is non-final.

Withdrawn rejections:

Applicant's amendments and arguments filed 12/18/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 51 recites: “final support substrate”. However, there is no initial support substrate so it is unclear what the “final support substrate” might actually be. Claims 51-62 are rejected as being indefinite because they are dependent on an indefinite base claim. The claims will be interpreted as they read on a support substrate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 51, 56, 59, 60 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (US 5411740).

Lee et al. disclose in Figures 1-4, reproduced below:

FIG. 1

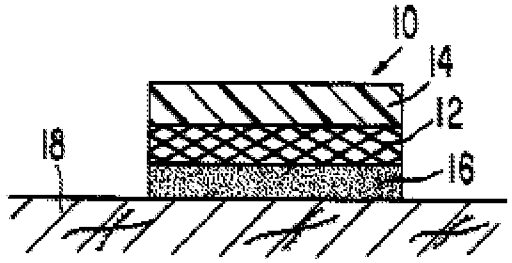


FIG. 2

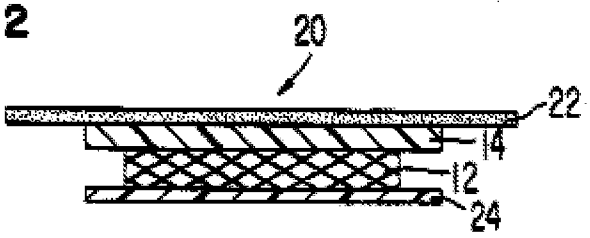


FIG. 3

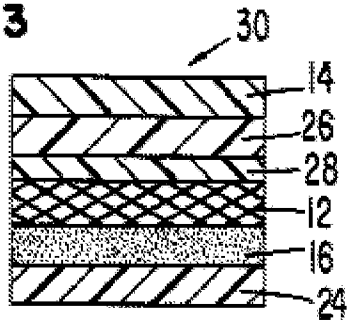
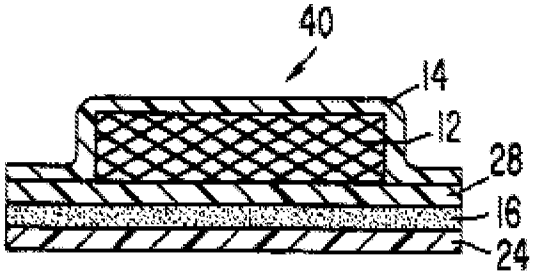


FIG. 4



a transdermal drug delivery device comprising a reservoir with an active agent and methods of treating neurogenic bladder disorders (Abstract and claims 1-28). As is clearly shown above in the Figures, for example Figure 2, device 20 contains an active ingredient reservoir 12. A backing layer 14 and adhesive overlay 22 maintain the device to the skin. A strippable release layer 24 is removed just prior to use (column 5, lines 24-49). Other materials are contemplated in the construction of the device (column 7, lines 15-33). Discs were cut of the laminate (column 9, lines 20-23).

In column 9, lines 10-23, it is disclosed that:

The devices for Example 1 were prepared as follows:

A. Formulation without a Permeation Enhancer

A formulation containing 30 wt % oxybutynin base in a matrix of EVA 40 (U.S.I. Chemicals, Illinois) was prepared by dissolving the oxybutynin base and EVA 40 in methylene chloride. The solution was poured onto a sheet of fluorocarbon diacrylate ("FCD")/polyester release liner to dry. The dried material was pressed to 5 mil (a. 0.1 mm) thickness between two sheets of FCD/polyester release liner at 75° C. The resulting film was laminated to a flexible cloth backing (spun laced polyester, 1.3 oz/yd^2), and 2.0 cm^2 discs were cut from the laminate.

So, in other words, a method of holding an active-agent containing composition (oxybutynin) comprising, providing a final support substrate (cloth backing) with one side in contact with a pattern adhesive, it has the pattern of the cloth backing, (column 9, lines 45-59), pouring the active agent solution on the a sheet of *fluorocarbon* diacryalte/polyester sheet (initial support substrate treated with a fluorochemical) and allowing it to dry before pressing it between two sheets of release liner (since it is a *release liner* it is removably attached otherwise it wouldn't release); attaching the resulting film to a flexible cloth backing (final support substrate) and segmenting the final support substrate into an array of discrete film segments; into discs. It is the Examiner's position that the adhesive has a single pattern. So, by making the device of Lee, it inherently performs the method of holding an active agent containing composition. In this way, claims 51, 56 and 62 are anticipated. In the absence of evidence to the contrary, the steps are performed in a continuous process, each disc contains a uniform amount of active agent thus anticipating instant claims 59 and 60.

Lee et al. teach in column 7, lines 26-33:

> The aforementioned patents describe a wide variety of materials which can be used for fabricating the various layers or components of the transdermal oxybutynin delivery devices according to this invention. This invention therefore contemplates the use of materials other than those specifically disclosed herein, including those which may hereafter become known to the art to be capable of performing the necessary functions.

The patents can be found in column 4, lines 47-54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 51-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 5411740) in view of Cartmell et al. (US (5489262) and Robertson et al. (US 3755042).

Applicant claims a method of holding an active agent-containing composition, the method comprising: providing a final support substrate, one side of the substrate in

contact with a pattern of adhesive; attaching a film including the active agent-containing composition to the final support substrate to place the film in removably attached contact with the pattern of adhesive; and segmenting the film attached to the final support substrate into an array of discrete film segments attached to the final support substrate.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Lee et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Cartmell et al. teach flexible wound dressing products containing a clear hydrogel material (Abstract; figures 1-6 and accompanying text; and claims 1-9). Method of manufacturing the device create the device and reads on the instant method of holding an active agent (see claims 1-9). Claim 1 recites:

What is claimed is:

1. A method of manufacturing a wound dressing product for a wound, comprising the steps of:

providing a transparent thin-film layer having a first side and a second side and further having a perimeter portion and a center portion;

coating said perimeter portion of said second side of said transparent layer with a first adhesive layer;

providing a backing layer having a first side and a second side;

coating said second side of said backing layer with a second adhesive layer;

providing a support layer having a first side and a second side, said support layer comprising a permeable fabric having a plurality of interstices therewithin;

laminating said first side of said support layer to said second side of said backing layer;

applying a hydrogel material to said second side of said support layer, wherein said hydrogel material penetrates said interstices to said first side of said support layer such that said hydrogel material resides on both said first side and said second side of said support layer, and whereby said backing layer, said support layer and said hydrogel material collectively form a reinforced hydrogel patch;

laminating said hydrogel patch to said center portion of said transparent layer, wherein said first side of said backing layer adheres to said second side of said transparent layer by means of said first adhesive layer;

providing a release liner having a first side and a second side;

providing at least one removable tab having a first side and a second side, so as to provide a grippable surface to facilitate the removal of said release liner from said transparent layer and to facilitate the handling of said wound dressing during application of said dressing to a wound;

laminating said first side of said tab to one edge of said perimeter portion of said second side of said transparent layer, whereby said first adhesive layer is positioned between said tab and said transparent layer;

laminating said first side of said release liner to said perimeter portion of said second side of said transparent layer, whereby said adhesive layer is positioned between said transparent layer and said release liner, and said tab portion is positioned between said adhesive layer and said release liner.

The release liner is preferably silicone coated (column 4, lines 35-37; column 7, lines 52-53). The patch is manufactured and cut to size (column 4, lines 27-29). Preserving the sterility of the wound dressing product is taught (column 7, lines 63-65).

Robertson et al. teach sterile packaging for medical devices with Teflon packaging (Abstract; figures 1 and 2 and text; and claims 1-4).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Lee et at. is that Lee et al. do not expressly teach sterilizing the device; making a pattern of parallel lines of the adhesive and enclosing the final support substrate in a container.

2. The difference between the instant application and Lee et at. is that Lee et al. do not expressly teach contacting the film removably attached to an initial support substrate with the pattern of adhesive, the initial support substrate located on a side of the film opposite the pattern of adhesive and delaminating the initial support substrate from the film.

3. The difference between the instant application and Lee et at. is that Lee et al. do not expressly teach a side of the initial support substrate in contact with the film is coated with silicon based compound. This deficiency is cured by the teachings of Cartmell et al.

4. The difference between the instant application and Lee et at. is that Lee et al. do not expressly teach superposing a sealing material over the array of discrete film segments attached to the final support substrate, the sealing material including a non-stick coating on at least a portion of the surface of the sealing material, wherein the non-stick coating reduces adhesion between the surface of the sealing material and at least one film segment when the sealing material contacts the at least one film segment. This deficiency is cured by the teachings of Robertson et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to sterilizing the device; making a pattern of parallel lines of the adhesive and enclosing the final support substrate in a container and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is common sense to provide a sterile device that will come into contact with human skin such that infection is not caused by the device and Cartmell et al. teach preserving the sterility of the product; absent unexpected results the adhesive will function as an adhesive whether it covers the entire surface, is placed in parallel lines or is in a polka dot arrangement; finally, placing the device in a container for commercial sale is the penultimate step in the marketing of the device which would be known and obvious to one of ordinary skill in the art.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to contacting the film removably attached to an initial support substrate with the pattern of adhesive, the initial support substrate located on a side of the film opposite the pattern of adhesive and delaminating the initial support substrate from the film and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results (*In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930)). The end result remains the same; a transdermal patch is made.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the device of Lee et al. with a side of the initial support substrate in contact with the film is coated with silicon based compound, as taught by Cartmell et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Lee et al. teach using any materials known (see above) and Cartmell et al. provide the silicone release liner. The expected result remains the same. A transdermal patch is made.

4. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to superposing a sealing material over the array of discrete film segments attached to the final support substrate, the sealing material including a non-stick coating on at least a portion of the surface of the sealing material, wherein the non-stick coating reduces adhesion between the surface of the sealing material and at least one film segment when the sealing material contacts the at least one film segment in the device of Lee et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the patch needs a packaging material for sale to the public and Robertson et al. provide a

non-stick packaging material that can be sterilized that can hold the patch(es) of Lee et al. Placing the patch(es) of Lee et al. in the package of Robertson et al. intrinsically meets the limitations of instant claim 61.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Examiner, Art Unit 1616